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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,430	08/22/2001	Mary Faris	511582005000	9082

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/935,430	Applicant(s) FARIS ET AL.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19,21-24 and 67-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19, 21-24 and 67-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendments and Arguments

1. Claims 19, 21-24 and 67-70 are pending.
Claims 19, 21-24 and 67 have been amended.
Claims 1-18, 20 and 25-66 have been cancelled.
Claims 19, 21-24 and 67-70 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections

Specification

3. The disclosure is no longer objected to because the specification now contains ATCC designations with corresponding numbers and the embedded hyperlinks and/or other form of browser-executable codes have been deleted.

Withdrawn Rejection

Claim Rejections - 35 USC § 112

4. The rejection of claims 19 and 67 set forth in section b of paragraph of 9, page 8 of the first action of the merits (FAOM) under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Sequence Compliance

5. This application contains a sequence disclosure on page 44 that is encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). This application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicants are requested to review the entire specification and amend it to include sequence identifiers ensuring that these added SEQ ID numbers are not new matter.

Maintained and New Grounds of Rejection

Claim Rejections - 35 USC § 112

6. The rejection of claims 19, 21-24, 67 and newly added claims 68-70 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained and made.

Applicants have amended the claims to include a sequence identifier, SEQ ID NO: 657. Applicants aver that they were in possession of the full scope of the claimed invention at the time the application was filed and that the amendment to the pending claims relate to the protein defined by SEQ ID NO: 656, the nucleotide encoding the

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protein regarded as SEQ ID NO: 657. The amendment, as well as these points of view have been carefully considered but found unpersuasive.

The amendment does not establish the nexus between the molecule designated as 158P1D7 and SEQ ID NO: 656, nor SEQ ID NO: 657. The specification cites that "...158P1D7 proteins are collectively referred to as the 158P1D7-related proteins", see page 14. The definition provided encompasses allelic variants, conservative substitution variants, analogs, homologs and fusion proteins that combine parts of different 158P1D7 proteins or fragments thereof. The written description in this instant case only sets the nucleic acid and polypeptide designated as SEQ ID NO: 656 and 657, respectively. The written description is not commensurate in scope with the claims that embody 158P1D7 molecules inclusive of allelic variants, conservative substitution variants, analogs, homologs and fusion proteins. The amendment does not clarify that 158P1D7 correlates to a specific sequence. Applicants may obviate the instant rejection by setting forth in the independent claims the following language, "...158P1D7 (SEQ ID NO: 657), comprising" and "...158P1D7 protein (SEQ ID NO: 657).

At the time the application was filed Applicants only had possession of 158P1D7 identified as SEQ ID NO: 656 and 657 and not 158P1D7 molecules that share less than 100% sequence identity with SEQ ID NO: 656 and 657. There is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

The full breadth of the claims do not meet the written description provision of 35 U.S.C. 112, first paragraph.

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7. The rejection of claims 19, 21-24, 67 and newly added claims 68-70 under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement commensurate with the scope of the claimed invention is maintained and made. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicants assert in view of the amendments made to the pending claims the instant rejection should be withdrawn. Applicants also assert that the Lazar article publication date "...undermines the observation by the Office that Lazar represents the 'true' state of the art". These points of view and arguments have been carefully considered, but found unpersuasive.

While Lazar was published approximately 10 years ago and the Examiner concurs with the Applicants that numerous developments have occurred during the intervening years the fact remains the same at the current times that an amino acid change or mutation can result in a complete loss of biological activity, change in structure or dramatic change in affinity and/or avidity. Applicants' amendment to the claims does not absolve the pending claims from rejection. While the specification suggests that 158P1D7 is SEQ ID NO: 656 (cDNA) and SEQ ID NO: 657 (protein), see page 6 the specification also lists 158P1D7 as representative of mutant molecules, see page 14. The amendment does not clarify that 158P1D7 correlates to a specific sequence. Applicants may obviate the instant rejection by setting forth in the independent claims the following language, "...158P1D7 (SEQ ID NO: 657), comprising"

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and "...158P1D7 protein (SEQ ID NO: 657). For the reasons of record and stated above the rejection is maintained and made.

9. The rejection of claims 19, 21-24, 67 and newly added claims 68-70 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained and made.

a. Applicants have amended claims 19 and 21, which contain the recitation "158P1D7" is indefinite. It still is not clear if "158P1D7" represents wild-type molecules or variants. Applicants may obviate this rejection by including a sequence identifying number directly after the recitation in question or clearly set forth in the claims that "158P1D7" is SEQ ID NO: 657.

Claim Rejections - 35 USC § 102

9. The rejection of claims 19, 21-24, 67 and newly added claims 68-70 rejected under 35 U.S.C. 102(e) as being anticipated by United States Patent Application Publication number 2004/0033504 (effective filing April 27, 2000) is maintained.

Applicants aver that the instant reference teaches sequences different from those disclosed as SEQ ID NO: 656 and SEQ ID NO: 657 and that the patent application publication does not anticipate the pending claims. These arguments have been considered, but found unpersuasive.

Applicants have not identified a particular epitope of SEQ ID NO: 657 or set forth so in the claims which amino acid residues of the protein are comprised within an immunogenic composition. Given the high sequence homology shared between Applicants' sequences and the patent publication's sequences the publication continues to anticipate the claims. United States Patent Application Publication #2004/0033504 discloses sequences 10 and 49, a polynucleotide and polypeptide sequence, respectively, which share at least 98% sequence identity to Applicants' SEQ ID NO: 656 and 657, see the FAOM's attached database sheets; page 10, Table 1; pages 26-28 and 62-64. SEQ ID NO: 656 and 657 are a polynucleotide and polypeptide sequences, respectively. The disclosed polynucleotides and polypeptides can be used in vaccines and in "method[s] for inducing an immunological response in a mammal that comprises inoculating the mammal with a polypeptide...adequate to produce antibody and/or T cell immune response, including for example, cytokine-cell producing T cells or cytotoxic T cells [CTL]...", see page 6, sections 0066, 0067 and 0070; bridging paragraph of columns 1 and 2 on page 6. Inherently, the CTL have the ability to kill an autologous cell that expresses the disclosed protein, SEQ ID NO: 657.

10. The rejection of claims 19, 21-24, 67 and newly added claims 68-70 under 35 U.S.C. 102(e) as being anticipated by WO 01/81363 (effective filing April 27, 2000) is maintained and made.

Applicants aver that the instant reference teaches sequences different from those disclosed as SEQ ID NO: 656 and SEQ ID NO: 657 and that the patent application

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publication does not anticipate the pending claims. These arguments have been considered, but found unpersuasive.

Applicants have not identified a particular epitope of SEQ ID NO: 657 or set forth so in the claims which amino acid residues of the protein are comprised within an immunogenic composition. Given the high sequence homology shared between Applicants' sequences and the WO document's sequences the publication continues to anticipate the claims. WO document 01/81363 discloses sequences 10 and 49, a polynucleotide and polypeptide sequence, respectively, which share at least 98% sequence identity to Applicants' SEQ ID NO: 656 and 657, see FAOM's attached database sheets; Sequence listing, pages 6, 7, 33 and 34 of 69. SEQ ID NO: 656 and 657 are a polynucleotide and polypeptide sequences, respectively. The disclosed polynucleotides and polypeptides can be used in vaccines and in "method[s] for inducing an immunological response in a mammal that comprises inoculating the mammal with a polypeptide...adequate to produce antibody and/or T cell immune response, including for example, cytokine-cell producing T cells or cytotoxic T cells [CTL]...", see page 13, lines 17-25 bridging paragraph of pages 13 and 14. Inherently, the CTL have the ability to kill an autologous cell that expresses the disclosed protein, SEQ ID NO: 657.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is

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(571) 272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (703) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER



Alana M. Harris, Ph.D.
6 July 2004